

REMARKS

The Final Office Action mailed June 10, 2002 has been received and reviewed. Claims 1-6, 9-15 and 19-23 are pending in the application. All claims stand rejected. Applicants propose to amend claim 1 and cancel claims 2, 13-15 and 19-23 as set forth herein. All amendments, including the cancellation of claims 2, 13-15 and 19-23, are made without prejudice or disclaimer.

Obviousness Rejections of Claims 1, 5, 19 and 20 over Haynes et al. in view of Wiedemann et al.

Claims 1, 5, 19 and 20 stand rejected under 35 U.S.C. § 103(a) as assertedly being unpatentable over Haynes et al. in view of Wiedemann et al. Claims 19 and 20 have been cancelled rendering the rejection of the claims moot. Partially in view of the proposed amendment to claim 1, applicants respectfully traverse the rejections.

As proposed to be amended, claim 1 includes the limitations of claim 2 and requires a thioester bond linking the antigen and the fatty acid or fatty acid peptide carrier compound. Since claim 2 was not rejected in view of Haynes et al. and Wiedemann et al., presently amended claim 1 should also be nonobvious as including the limitations of claim 2. Further, since neither Haynes et al. nor Wiedemann et al., alone or in combination, teaches or suggests a thioester bond linking the antigen to the fatty acid or fatty acid peptide carrier compound, a *prima facie* case of obviousness cannot be established.

Dependent claim 5 is nonobvious at the very least as depending from nonobvious independent claim 1. (*See, In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)).

Reconsideration and withdrawal of the obviousness rejections of claim 1 and claim 5 depending therefrom are thus requested.

Obviousness Rejections of claims 1-6, 9, 10, 12 and 19-23 over Meloen et al. in view of Wiedermann et al.

Claims 1-6, 9, 10, 12 and 19-23 stand rejected under 35 U.S.C. § 103(a) as assertedly being unpatentable over Meloen et al. in view of Wiedermann et al. Claims 2 and 19-23 have

been cancelled rendering the rejection of these claims moot. Applicants propose to amend claim 1, and partially in view thereof, respectfully traverse the rejections.

A *prima facie* case of obviousness cannot be established with regard to presently amended claim 1 since the cited references do not, alone or in combination, teach or suggest all the limitations of claim 1. For instance, amended claim 1 requires a thioester bond linking the antigen to the fatty acid or fatty acid peptide carrier compound. Neither Meloen et al. nor Wiedermann et al. teaches or suggests a thioester bond as required to render claim 1 obvious. Accordingly, a *prima facie* case of obviousness cannot be established.

Dependent claims 3-6, 9, 10 and 12 are nonobvious at the very least as depending from nonobvious independent claim 1. (*See, In re Fine, supra*).

Accordingly, reconsideration and withdrawal of the obviousness rejections of claims 1, 3-6, 9, 10 and 12 are requested.

Anticipation Rejections of Claims 1, 3, 5, 12 and 13 by Golding

Claims 1, 3, 5, 12 and 13 stand rejected under 35 U.S.C. § 102(e) as assertedly being anticipated by Golding. Claim 13 has been cancelled rendering the rejection thereof moot. Partially in view of the proposed amendment to claim 1, applicants respectfully traverse the rejections.

As proposed to be amended, independent claim 1 includes the limitations of claim 2 which was not deemed anticipated by Golding. Claim 1 further cannot be anticipated since Golding does not disclose each and every limitation of claim 1. For instance, claim 1 requires the antigen to dissociate from the fatty acid or fatty acid peptide carrier compound under physiological conditions after administration to a subject.

The Office Action relies on inherency to anticipate claim 1: "Golding's thioester linkage represents a labile bond that dissociates under physiological conditions is inherent from the disclosure of Golding. The functions of lability and dissociation are considered as inherent properties inseparable from the prior art thioester linkage." (Final Office Action, page 6). "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic

necessarily flows from the teachings of the applied prior art.” (M.P.E.P. § 2112, citing *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (Emphasis in original)). Since the Office Action does not provide a basis in fact or technical reasoning indicating that the thioester bond of Golding is labile or dissociates under physiologic conditions, Golding cannot be considered to inherently disclose the limitations of claim 1 as required for anticipation.

Regarding dependent claims 3, 5, and 12, they are novel, at the very least, as depending from novel independent claim 1. Reconsideration and withdrawal of the anticipation rejections of claims 1, 3, 5 and 12 are thus requested.

Anticipation Rejections of Claims 1-5, 12, 19, 20, 22 and 23 by Jung et al.

Claims 1-5, 12, 19, 20, 22 and 23 stand rejected under 35 U.S.C. § 102(b) as assertedly being anticipated by Jung et al. Claims 2, 19, 20, 22 and 23 have been cancelled rendering the rejections thereof moot. The rejections are respectfully traversed, at least partially, in view of the proposed amendment to claim 1.

Presently amended claim 1 requires a thioester linkage directly connecting the antigen and the fatty acid or fatty acid-peptide carrier compound, wherein the antigen dissociates from the fatty acid or fatty acid-peptide carrier under physiologic conditions. Amended claim 1 is not anticipated since Jung et al. does not disclose a thioester linkage that connects an antigen and a fatty acid or fatty acid-peptide carrier compound. Further, Jung et al. does not disclose the antigen dissociating from the fatty acid or fatty acid-peptide carrier under physiologic conditions.

The Office Action indicates the “functions of lability and dissociation are considered as inherent properties inseparable from the prior art disulfide linkage.” (Office Action, page 6). However, since a basis in fact or technical reasoning has not been provided in the Office Action indicating that the functions of lability and dissociation necessarily flow from Jung et al., Jung et al. does not inherently disclose the limitations. (See, M.P.E.P. § 2112, *supra*).

Accordingly, reconsideration and withdrawal of the anticipation rejections of independent claim 1, and claims 3-5 and 12 depending therefrom, are requested.

Anticipation Rejections of Claims 1-5, 9, 10, 19, 20 and 22 by Chang et al.

Claims 1-5, 9, 10, 19, 20 and 22 stand rejected under 35 U.S.C. § 102(b) as assertedly being anticipated by Chang et al. Claims 2, 19, 20 and 22 have been cancelled rendering the rejections thereof moot. Partially in view of the proposed amendment to claim 1, the rejections are respectfully traversed.

Presently amended claim 1 is not anticipated by Chang et al. as the limitation of a thioester bond directly linking an antigen to a fatty acid or fatty acid-peptide carrier compound is not disclosed in Chang et al. Claims 3-5, 9 and 10 are not anticipated as depending from novel independent claim 1.

Reconsideration and withdrawal of the anticipation rejections of claim 1, and claims 3-5, 9 and 10 depending therefrom, are thus requested.

Anticipation Rejections of Claims 1, 3-5, 12, 19, 20, 22 and 23 by Shen et al.

Claims 1, 3-5, 12, 19, 20, 22 and 23 stand rejected under 35 U.S.C. § 102(e) as assertedly being anticipated by Shen et al. Claims 19, 20, 22 and 23 have been cancelled rendering the rejections thereof moot. Applicants respectfully traverse the rejections, at least partially, in view of the proposed amendment to independent claim 1.

As proposed to be amended, claim 1 includes the limitations of claim 2 which was not deemed anticipated by Shen et al. Further, Shen et al. does not disclose an antigen directly linked by a thioester bond to a fatty acid or fatty acid-peptide carrier compound as required for anticipation. Regarding claims 3-5 and 12, they are not anticipated, at the very least, as depending from novel independent claim 1.

Accordingly, reconsideration and withdrawal of the anticipation rejections of claims 1, 3-5 and 12 are respectfully requested.

Anticipation Rejections of Claims 1, 3 and 5 by Staufenbiel

Claims 1, 3 and 5 stand rejected under 35 U.S.C. § 102(b) as assertedly being anticipated by Staufenbiel. Partially in view of the proposed amendment to claim 1, the rejections are respectfully traversed.

As proposed to be amended, claim 1 includes the limitations of claim 2 which was not deemed anticipated by Staufenbiel. Claim 1 is further not anticipated since Staufenbiel does not disclose a vaccine comprising an antigen directly linked to a fatty acid or fatty acid-peptide carrier compound, wherein the antigen dissociates from the fatty acid or fatty acid-peptide carrier compound after administration to a subject. Claims 3 and 5 are not anticipated, at the very least, as depending from novel independent claim 1.

Reconsideration and withdrawal of the anticipation rejections of claims 1, 3 and 5 are thus requested.

Anticipation Rejections of Claims 1, 3 and 5 by Wan et al.

Claims 1, 3 and 5 stand rejected under 35 U.S.C. § 102(b) as assertedly being anticipated by Wan et al. The rejection is respectfully traversed, at least partially, in view of the proposed amendments to claim 1.

Claim 1 is not anticipated since Wan et al. does not disclose a labile, thioester bond between an antigen and a fatty acid or fatty acid-peptide carrier compound which dissociates under physiologic conditions. Further, since presently amended claim 1 includes the limitations of claim 2, which was not deemed anticipated by Wan et al., claim 1 is not anticipated. Claims 3 and 5 are novel at the very least as depending from claim 1.

In view thereof, reconsideration and withdrawal of the anticipation rejections of claims 1, 3 and 5 are requested.

Obviousness Rejections of Claims 13, 14, 19, 20 and 23 over Shen et al. or Chang et al. in view of Wong and/or Staufenbiel

Claims 13, 14, 19, 20 and 23 stand rejected under 35 U.S.C. § 103(a) as assertedly being unpatentable over Shen et al. or Chang et al. in view of Wong and/or Staufenbiel. Claims 13, 14, 19, 20 and 23 have been cancelled rendering the rejections thereof moot.

Obviousness Rejections of Claims 15 and 21 over Chang et al. in view of Wong and further in view of Meloen et al.

Claims 15 and 21 stand rejected under 35 U.S.C. § 103(a) as assertedly being unpatentable over Chang et al. in view of Wong and further in view of Meloen et al. Claims 15 and 21 have been cancelled rendering the rejection of the claims moot.

Obviousness Rejections of Claims 1, 3, 4, 6, 9, 10, 19 and 21 over Chang et al. in view Russell-Jones et al. or Meloen et al.

Claims 1, 3, 4, 6, 9, 10, 19 and 21 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Chang et al. in view of Russell-Jones et al. or Meloen et al. Claims 19 and 21 have been cancelled rendering the rejections thereof moot. Applicants propose to amend claim 1 and in view thereof, respectfully traverse the rejections.

Presently amended claim 1 is not rendered obvious by the cited references since as proposed to be amended, claim 1 includes the limitations of claim 2 which was not deemed obvious in view of the cited references. Further, the cited references do not, alone or in combination, teach or suggest each and every limitation of claim 1 as required to establish a *prima facie* case of obviousness. Since none of the cited references teach or suggest an antigen linked by a labile, thioester bond to a fatty acid or fatty acid-peptide carrier compound, claim 1 is not rendered obvious by the cited references.

Claims 3, 4, 6, 9 and 10 are nonobvious, at the very least, as depending from nonobvious independent claim 1. (*See, In re Fine, supra*).

Accordingly, reconsideration and withdrawal of the obviousness rejections of claims 1, 3, 4, 6, 9 and 10 are requested.

ENTRY OF AMENDMENTS

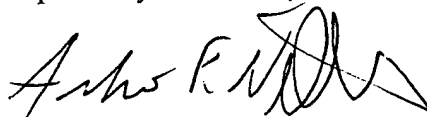
The proposed amendments to claim 1 should be entered because the amendments are supported by the as-filed specification and drawings and do not add any new matter to the application. Further, the amendments should not raise new issues or require a further search since the subject matter of the amendment was originally presented in dependent claim 2. The

amendments should thus place the claims in condition for allowance. If the Examiner determines that the amendments do not place the application in condition for allowance, entry is respectfully requested since they certainly remove issues for appeal.

CONCLUSION

In view of the proposed amendments and remarks presented herein, applicants respectfully submit that the amended claims define patentable subject matter. If questions remain after consideration of the foregoing, the Examiner is kindly requested to contact applicants' attorney at the address or telephone number given herein.

Respectfully submitted,



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Date: November 12, 2002
AFN/afn
Document in ProLaw

MARKED UP VERSION OF CLAIMS SHOWING CHANGES MADE

1. (Twice Amended) A vaccine comprising an antigen and a fatty acid or fatty acid-peptide carrier compound which are directly linked by a thioester [or a disulfide] bond that is labile and dissociates under physiological conditions, wherein said antigen dissociates from said fatty acid or fatty acid-peptide carrier compound after administration to a subject.